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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,353	03/07/2005	Qing Yang	APL-101/US	8302

30869 7590 02/01/2011
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EXAMINER

NEGIN, RUSSELL SCOTT

ART UNIT	PAPER NUMBER
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1631

NOTIFICATION DATE	DELIVERY MODE
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02/01/2011

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ptomail@lumen.com

Office Action Summary	Application No. 10/523,353	Applicant(s) YANG, QING	
	Examiner Russell S. Negin	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 November 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 71-74 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 71-74 is/are rejected.
- 7) ☒ Claim(s) 71 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/29/10</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Comments

Applicants' amendments and request for reconsideration in the communication filed on 29 November 2010 are acknowledged and the amendments are entered.

Claims 71-74 are pending and examined in the instant Office action.

Information Disclosure Statement

The information disclosure statement filed on 29 November 2010 has been considered.

Withdrawn Objections/Rejections

Since applicant cancelled all of the previously pending claims and added four new claims (claims 71-74), all of the previous rejections and objections are hereby withdrawn since all of the previously pending claims no longer exist.

Claim Objections

The following objections are necessitated by amendment:

Claim 71 is objected to because of the following informalities:

The tense of the verb in step e (determine) of claim 71 should be present progressive (***determining***) rather than present (***determine***) to match the tenses of the verbs in the other steps of the claim.

The phrase bridging lines 1 and 2 of step e of claim 71 should be “**said** C(t)” rather than “**a said** C(t)”.

The phrase in line 3 of step h of claim 71 should be “wherein **for**” rather than “wherein **fro**”.

The phrase beginning step i of claim 71 should be “providing **an**” rather than “providing **in**”.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

INDEFINITENESS

The following rejections are necessitated by amendment:

Claims 71-74 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

While steps c and d of claim 71 recite the function $AFT_a(t)$ as an arterial input function, this function is never used as the arterial input function in the equations in claims 71-74. To the contrary, the arterial input function $AlF_a(t)$ is used as the arterial input function. Even though claims 71-74 never define a relation between $AFT_a(t)$ and $AlF_a(t)$, it is interpreted, for the purpose of examination, that these functions are equal.

While steps k, l, and, m of claim 71 recite using four adjustable parameters and their manipulations both to optimize agreement between measured and simulated functions and to better determine perfusion indices, the claims never clearly state which of the plethora of parameters and functions correspond to the four adjustable parameters. While page 5, line 20-25; page 9, lines 16-20; page 19, lines 21-30; and page 21, lines 22-31 of the specification list potential adjustable parameters, these lists encompass many more than four adjustable parameters. In addition, it is unclear if the parameters k_H , H_a , and H_t (in step d of claim 71), whose ranges are approximate, also may be considered “adjustable parameters.” It is noted that while the specification differentiates adjustable from fixed values, no such limitation is recited in the instant claims.

ENABLEMENT

The following rejections are necessitated by amendment:

Claim 71-74 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. While the claims recite modifying four adjustable parameters to optimize agreement between measures and simulated results, it is not known as to which four parameters are optimized.

1. Step k of claim 71 recites iteratively optimizing four adjustable parameters until the best agreement between measured and simulated results is obtained. However, since the claim recites many more than four parameters, it is not known as to which four parameters are the designated “adjustable parameters.” Additionally, the claim does not even designate a set of potentially adjustable parameters from which the subset of four adjustable parameters may be selected.

2. While page 5, line 20-25; page 9, lines 16-20; page 19, lines 21-30; and page 21, lines 22-31 of the specification list adjustable parameters, these lists encompass many more than four parameters. In addition, while not included in the sets of adjustable parameters in the specification, it is unclear if the parameters k_H , H_a , and H_t (in step d of claim 71), whose ranges are approximate, also may be considered “adjustable parameters.” It is noted that while the specification differentiates adjustable from fixed values, no such limitation is recited in the instant claims. Additionally, none of the individual lists in the specification consist of only four parameters.

3. It is noted that the prior art of Thompson et al. [Circulation Research, volume 14, 1964, pages 502-515; on IDS] teaches simulating transit times for indicator dilution curves. Specifically, the equations (such as equations 1-3) of Thompson et al. unambiguously define the role of each variable, parameter, and function underneath each equation.

4. Claim 71 iteratively modifies four adjustable parameters until agreement between measured and simulated concentration profiles of contrast agent in an artery. However, the claims recite many more than four parameters; the claims also do not differentiate between adjustable and fixed parameters. While the specification differentiates between adjustable and fixed parameters, the specification discloses many more than four adjustable parameters. In the absence of this specific guidance in the claims and specification (unlike in the example prior art document of Thompson et al.), one must guess as to which four parameters are the four adjustable parameters that are optimized in claim 71. Such guessing amounts to UNDUE EXPERIMENTATION.

In view of the above, it is the Examiner's position that with the insufficient guidance and working examples and in view of unpredictability and the state of art one skilled in the art could not make and/or use the invention with the claimed breadth without an undue amount of experimentation.

Response to Arguments

Applicant's arguments with respect to the instantly set of claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

No claim is allowed.

It is noted that the equation for the average tissue input residue function $R_s(t)$ in the third line of step i of claim 71 is not taught or suggested in the prior art.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the central PTO Fax Center. The faxing of such pages must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Negin, whose telephone number is (571) 272-

1083. The examiner can normally be reached on Monday-Friday from 8:30 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Marjorie Moran, Supervisory Patent Examiner, can be reached at (571) 272-0720.

Information regarding the status of the application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information on the PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Russell S. Negin/
Primary Examiner, Art Unit 1631
27 January 2011